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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,917	10/23/2003	Ruchika Singhal	1023-234US01	6514

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SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT PAPER NUMBER

3762

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/691,917		SINGHAL ET AL.	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: <u>09292004 4/16/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: "patient 12" should read "patient 14" in paragraph 0021.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-14 and 19-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In regards to claim 8, the term "the therapy device" is lacking antecedent basis. Examiner is interpreting this term as "the medical device".

5. Claim 19 is vague because it is unclear how the processor receives a command because no element has been set forth to send commands. Examiner has interpreted this as being functional language that should read "a processor adapted to receive a command". The phrase "therapy information" is inferentially included, rendering it unclear whether this element is part of the claimed invention. The phrase "delivery of therapy" is vague because no element has been set forth to deliver therapy.

6. In regards to claim 20, the phrase "receiving indications" is vague because no element has been set forth to receive indications.
7. In regards to claim 30 it is unclear what is "changing the therapy". Examiner has interpreted this as a typographical error wherein the claim should read: "wherein the device changes the therapy parameter".
8. Claim 31 is vague because it is unclear how the processor "receives the value" because no element has been set forth to receive values.
9. Claim 34 is vague because it is unclear how the processor "presents the defined event" because no element has been set forth to present events.
10. In regards to claim 37, "implantable medical device" is inferentially included, rendering it unclear whether this element is part of the claimed invention.
11. Claims 38 and 49 are vague because it is unclear whether Applicant is claiming a person, which is non-statutory subject matter.
12. Claims 39-49 are vague because it is unclear whether Applicant is claiming instructions, medium, or both. Furthermore, it is unclear whether Applicant is claiming a processor. Claims 40-49 recite "a programmable processor". It is unclear whether this is the previously recited processor. It is recommended to recite "the programmable processor".

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-10, 12, 15, 18-29, 35, 37-46, and 49 are rejected under 35

U.S.C. 102(b) as being anticipated by Sheldon (US 5,593,431 hereinafter "Sheldon").

15. In regards to claims 1, 19 and 39, Sheldon discloses entering a learning mode (element 210 and col. 10, line 11), defining an event and associating therapy with the event (Fig. 9), and providing therapy based on the detected event (col. 12, line 55).

16. In regards to claims 2, 3, 20, 21, 40 and 41, the user indicates the event, which is a posture undertaken by the patient (Fig. 13). The user must inherently indicate which posture is being defined.

17. In regards to claims 4, 22 and 42, defining an event comprises monitoring the output of a sensor reflective of a physiological parameter (72, 74, and 76), defining an event based on the output (col. 12, line 12), and detecting an event comprises monitoring the sensor and comparing it to the defined event (Fig. 9).

18. In regards to claims 5 and 24, the sensor is an accelerometer (abstract).

19. In regards to claims 6 and 23, the output reflects posture (col. 12, line 55).

20. In regards to claims 7, 26 and 43, the sensor output is recorded over a period of time (col. 10, line 17).

21. In regards to claims 8, 27 and 44, a value of a parameter that controls delivery of therapy is recorded (col. 10, line 17) and associated with a defined event. Examiner is interpreting posture as controlling delivery of therapy.

22. In regards to claims 9, 10, 28, 29, 45 and 46, various postures are recorded, so "a change to the parameter" is recorded.

23. In regards to claim 12, the device is an implantable medical device (Fig. 3) and a programmer receives a change to the therapy parameter (the various changes in posture) via a programmer (col. 10, line 11).

24. In regards to claims 15 and 35, providing therapy comprises suspending delivery of therapy (by increasing the escape interval, col. 12, line 59).

25. In regards to claims 18, 38 and 49 the user is one of a clinician and patient (col. 10, line 13).

26. In regards to claim 25 the accelerometer is a multi-axis accelerometer (col. 4, line 18).

27. In regards to claim 37, the device comprises a programmer (100).

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 14, 16, 17, 31-34, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon. Sheldon discloses the essential features of the claimed invention, including changing delivery of therapy based on a change in a parameter and a time (col. 13, line 52), presenting parameter data to a physician (col. 15, line 59), and deriving the events with markers over time (Fig. 15). Sheldon does not expressly disclose receiving a time from the user or presenting the defined events to the clinician as markers within a timing diagram. It is well known in the art to provide user-customizable time intervals to provide a desired level of hysteresis in signal acquisition and presenting acquired data to a clinician to enable the clinician to modify parameters or make a diagnosis. Therefore, it would have been obvious to modify Sheldon's invention by providing user-customizable time intervals to provide a desired level of hysteresis in signal acquisition and presenting the acquired data shown in Figure 15 to a clinician to enable the clinician to modify parameters or make a diagnosis.

31. Claims 11, 13, 30, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon in view of Schallhorn (US 6,120,467 hereinafter "Schallhorn"). Sheldon discloses the essential features of the claimed invention, but does not expressly disclose changing a therapy parameter in response to recorded changes in the therapy parameter or a medical device that is a neurostimulator and the

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therapy parameter is pulse amplitude, width, or rate. Schallhorn teaches of providing a neurostimulator with a means to change a therapy in response to recorded changes in the therapy parameter (Fig. 5 and col. 5, line 13) to provide customized therapy to the patient and utilizing a neurostimulator wherein a therapy parameter is pulse width (col. 2, line 28) to provide a means to adjust pain therapy in relation to activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sheldon's invention with a means to change a therapy in response to recorded changes in the therapy parameter to provide customized therapy to the patient and utilizing a neurostimulator wherein a therapy parameter is pulse width to provide a means to adjust pain therapy in relation to activity.

Conclusion

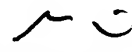
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



GEORGE R. EVANS JR.
PRIMARY EXAMINER
2/24/6